PATENT
Docket No.: 48317USA1N.033

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL. Group Art Unit:

Express Mail Label No.: EL 597 086 703 US

Filed: April 18, 2001 Examiner:

For: FILTERING FACE MASK THAT HAS A NEW EXHALATION VALVE

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please amend this application as set forth below.

IN THE TITLE:

Please replace the present title with the following title: --FILTERING FACE MASK THAT HAS A NEW EXHALATION VALVE--.

IN THE SPECIFICATION:

Page 1, lines 8-10, delete the sentence and insert the following:

This is a division of United States Patent Application Serial No. 08/240,877 filed May 11, 1994, which is a division of Application No. 07/981,244, filed November 25, 1992 (now U.S. Patent No. 5,325,892), which is a continuation-in-part of Application No. 07/891,289, now abandoned.

Page 3, please amend the paragraph beginning at line 7 and ending at line 9:

wherein, the fluid-permeable face mask can demonstrate a negative pressure drop when air is passed into the filtering face mask with a velocity of at least 8 m/s under a normal exhalation test.

Page 7, please amend the paragraphs beginning at line 15 and ending at line 36:

When a wearer of a filtering face mask **10** exhales, exhaled air passes through the mask body **12** and exhalation valve **14**. Comfort is best obtained when a high percentage of the exhaled air passes through exhalation valve **14**, as opposed to the filter media of mask body **12**. Exhaled air is expelled through valve **14** by having the exhaled air lift flexible flap **24** from valve seat **26**. Flexible flap **24** is attached to valve seat **26** at a first stationary portion **28** of flap **24**, and the remaining circumferential edge of flexible flap **24** is free to be lifted from valve seat **26** during exhalation. The circumferential edge segment that is associated with the stationary portion **28** remains at rest during an exhalation. As the term is used herein, "flexible" means the flap can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., FIG. 5). A flap that is not self-supporting will tend to drape towards the ground at about 90 degrees from the horizontal.

As shown in FIGs. 3 and 4, valve seat **26** has a seal ridge **30** that has a seal surface **31** to which the flexible flap **24** makes contact when a fluid is not passing through the valve **14**. An orifice **32** is located radially inward to seal ridge **30** and is circumscribed thereby. Orifice **32** can have cross-members **34** that stabilize seal ridge **30** and ultimately valve **14**. The cross-members **34** also can prevent flexible flap **24** from inverting into orifice **32** under reverse air flow, for example, during inhalation. When viewed from a side elevation, the surface of the cross-members **34** is slightly recessed beneath (but may be aligned with) seal surface 31 to ensure that the cross members do not lift the flexible flap **24** off seal surface 31 (see FIG. 3).

Page 10, please amend the paragraph beginning at line 3 and ending at line 12:

Valve seat **26** preferably is made from a relatively light-weight plastic that is molded into an integral one-piece body. The valve seat can be made by injection molding techniques. The surface **31** of the seal ridge **30** that makes contact with the flexible flap **24** (the contact or seal surface) is preferably fashioned to be substantially uniformly smooth to ensure that a good seal occurs. The contact surface preferably has a width great enough to form a seal with the flexible flap **24** but is not so wide as to allow adhesive forces caused by condensed moisture to significantly make the flexible flap

24 more difficult to open. The width of the contact surface, preferably, is at least 0.2 mm, and preferably is in the range of about 0.25 mm to 0.5 mm.

Page 14, please amend the paragraph beginning at line 33 and ending on page 15 at line 25:

Exhalation valve **14** can be provided with a valve cover to protect the flexible flap **24**, and to help prevent the passage of contaminants through the exhalation valve. In FIG. 7, a valve cover **50** is shown which can be secured to exhalation valve **14** by a friction fit to wall **44**. Valve cover **50** also can be secured to the exhalation valve **14** by ultrasonic welding, an adhesive, or other suitable means. Valve cover **50** has an opening **52** for the passage of a fluid. Opening **52** preferably is at least the size of orifice **32**, and preferably is larger than orifice **32**. The opening **52** is placed, preferably, on the valve cover **50** directly in the path of fluid flow **36** so that eddy currents are minimized. In this regard, opening **52** is approximately parallel to the path traced by the free end **38** of flexible flap **24** during its opening and closing. As with the flexible flap **24**, the valve cover opening **52** preferably directs fluid flow downwards so as to prevent the fogging of a wearer's eyewear. All of the exhaled air can be directed downwards by providing the valve cover with fluid-impermeable side walls **54**. Opening **52** can have cross-members **56** to provide structural support and aesthetics to valve cover **50**. A set of ribs **58** can be provided on valve cover **50** for further structural support and aesthetics. Valve cover **50** can have its interior fashioned such that there are female members (not shown) that mate with pins **41** of valve seat **14**. Valve cover **50** also can have a surface (not shown) that holds flexible flap **24** against flap-retaining surface **40**. Valve cover **50** preferably has fluid impermeable ceiling **60** that increases in height in the direction of the flexible flap from the fixed end to the free end. The interior of the ceiling **60** can be provided with a ribbed or coarse pattern or a release surface to prevent the free end of the flexible flap from adhering to the ceiling **60** when moisture is present on the ceiling or the flexible flap. The valve cover design **50** is fully shown in U.S. Design Patent Application 29/000,382. Another valve cover that also may be suitable for use on a face mask of this invention is shown in Design Patent Application 29/000,384. The disclosures of these applications are incorporated here by reference.

Page 20, please amend the paragraph beginning at line 24 and ending at line 33:

The exhalation valve of Example 1 was mounted to a 3M 8810 filtering face mask such that the exhalation valve was positioned on the mask body directly opposite to where a wearer's mouth would be when the mask is worn. The airflow through the nozzle was increased to approximately 80 l/min to provide an airflow velocity of 8.3 meters per second (m/s). At this velocity, zero pressure drop was achieved inside the face mask. An ordinary person will exhale at moderate to heavy work rates at an approximate air velocity of about 5 to 13 m/s depending on the opening area of the mouth. Negative and relatively low pressures can be provided in a face mask of this invention over a large portion of this range of air velocity.

Page 22, please replace Table 2:

Examples	*Volume Flow (liters/minute)*	*Pressure Drop (Pa) Nozzle Area: 18.1 cm²*	*Pressure Drop (Pa) Nozzle Area: 2.26 cm²*	*Pressure Drop (Pa) Nozzle Area: 0.96 cm²*	*% Total Flow Nozzle Area: 18.1 cm²*	*% Total Flow Nozzle Area: 2.26 cm²*	*% Total Flow Nozzle Area: 0.95 cm²*
8	12	9.02	8.92	8.92	1	2	2
9	24	15.09	14.21	11.17	19	24	39
10	48	18.62	14.99	4.31	30	60	87
11	60	20.48	15.09	-1.76	56	68	102
12	72	22.34	14.80	-7.55	61	73	112
13	80	24.01	14.41	-12.94	62	77	119

IN THE CLAIMS:

Please cancel claims 1-32.

Kindly add claims 33-68 to this patent application:

33. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer, the mask body comprising a filtration layer through which inhaled air may pass before being inhaled by a wearer of the face mask; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve allowing air exhaled by a wearer to pass from an interior of the mask body to its exterior without having to pass through the filtration layer, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is circumscribed by the seal surface; and

(2) a single flexible flap that has one stationary portion and one free portion and a circumferential edge, the circumferential edge having a first segment that is associated with the one stationary portion of the flap so as to remain at rest during an exhalation and having a second segment that is associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second segment of the circumferential edge also being located below the first segment when the filtering face mask is worn on a person, the flexible flap being mounted to the valve seat such that the one free portion of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice.

34. The filtering face mask of claim 33, wherein the flexible flap is not wholly circular in configuration when viewed from the front.

35. The filtering face mask of claim 33, wherein the second segment of the circumferential edge has a circular curvature that corresponds to a circularly shaped seal surface disposed beneath the second segment of the flap's circumferential edge.

36. The filtering face mask of claim 33, wherein the valve seat has a flap retaining surface, the flexible flap being mounted to the flap-retaining surface.

37. The filtering face mask of claim 36, wherein the flap retaining surface is planar.

38. The filtering face mask of claim 37, further comprising a valve cover, the valve cover having an opening that allows exhaled air to pass therethrough and also having a surface that holds the flexible flap against the flap-retaining surface on the valve seat.

39. The filtering face mask of claim 38, wherein the flexible flap is secured to the valve seat by mechanical clamping.

40. The filtering face mask of claim 39, wherein the flap-retaining surface is disposed on the valve seat on one side of the seal surface.

41. The filtering face mask of claim 37, wherein the flap-retaining surface includes two securement points both disposed outside a region encompassed by the orifice.

42. The filtering face mask of claim 36, wherein the curvature in the flexible flap extends from a point where the flap is mounted to the valve set to a second point where the free portion of the flexible flap makes contact with the seal surface.

43. The filtering face mask of claim 42, wherein the curvature does not have an inflection point.

44. The filtering face mask of claim 33, further comprising a valve cover that has an opening that permits exhaled air to pass therethrough, the valve cover also having a fluid-impermeable ceiling that increases in height in the direction of the flexible flap from the first segment of the circumferential edge towards the second segment of the edge.

45. The filtering face mask of claim 41, wherein the opening in valve cover has cross-members extending thereacross and is positioned directly in the path of fluid flow approximately parallel to the path traced by the second segment of the circumferential edge during opening and closing of the free portion of the flexible flap.

46. The filtering face mask of claim 33, wherein the valve seat's orifice is circular and has cross-members disposed within the orifice to assist in preventing the flexible flap from being drawn into the orifice during an inhalation.

47. The filtering face mask of claim 33, wherein the valve seat includes one or more cross members that are disposed within the orifice of the valve seat.

48. The filtering face mask of claim 46, wherein the cross members are slightly recessed beneath the seal surface when viewed from a side elevation.

49. The filtering face mask of claim 46, wherein the shape of the orifice, when viewed from the front, does not wholly correspond to the shape of the seal surface.

50. The filtering face mask of claim 33, wherein the valve seat includes a flange portion that defines a mounting surface for the valve seat, which surface extends 360° around the valve seat at its base and enables the valve seat to be secured to the mask body.

51. The filtering face mask of claim 33, wherein the flexible flap assumes a curved profile, when in its closed state, that extends in from where the flexible flap contacts a retaining surface on the valve seat to where the second portion of the flexible flap contacts the seal surface of the valve body portion.

52. The filtering face mask of claim 33, wherein the flap retaining surface is oriented transversely relative to the orifice.

53. The filtering face mask of claim 52, wherein the flap retaining surface is positioned adjacent one side of the orifice.

54. The filtering face mask of claim 33, wherein the valve seat includes a peripheral flange for mounting the exhalation valve to the mask body, the valve seat also having a seal ridge that extends upwardly so that the seal surface is upwardly spaced relative to the peripheral flange.

55. The filtering face mask of claim 33, wherein the flexible flap is mounted to the valve seat in cantilever fashion.

56. The filtering face mask of claim 33, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

57. The filtering face mask of claim 33, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface, and wherein the flexible flap would normally assume a flat configuration when no forces are applied to it.

58. The filtering face mask of claim 57, wherein the bias towards the seal surface is generated by the mounting of the flap to the valve seat.

59. The filtering face mask of claim 58, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

60. The filtering face mask of claim 59, wherein the flexible flap is made from a crosslinked polyisoprene.

61. The filtering face mask of claim 58, wherein the flexible flap has a Shore A hardness of about 30 to 50 and has a generally uniform thickness of about 0.2 to 0.8 millimeters.

62. The filtering face mask of claim 33, wherein the flexible flap is longer in the direction extending from the first segment of the circumferential edge to the second segment.

63. The filtering face mask of claim 33, wherein the first segment of the flexible flap is about 10 to 25 percent of the total circumferential edge of the flexible flap, and the second segment is about 75 to 90 percent being free to be lifted from the seal surface.

64. The filtering face mask of claim 44, wherein the flexible flap and valve cover are positioned on the valve seat such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

65. The filtering face mask of claim 33, wherein the mask body is cup-shaped and comprises (1) a shaping layer for providing structure to the mask, and (2) a filtration layer.

66. The filtering face mask of claim 33, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

67. The filtering face mask of claim 33, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

68. The filtering face mask of claim 67, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth.

IN THE ABSTRACT:

Please delete the Abstract and replace with the following Abstract:

A filtering face mask that comprises a mask body that is adapted to fit over the nose and mouth of a wearer, the mask body comprising a filtration layer through which inhaled air may pass before being inhaled by a wearer of the face mask; and an exhalation valve that is attached to the mask body, the exhalation valve allowing air exhaled by a wearer to pass from an interior of the mask body to its exterior without having to pass through the filtration layer, the exhalation valve comprising: a valve seat that comprises: a seal surface; and an orifice that is circumscribed by the seal surface; and a single flexible flap that has one fixed portion and one free portion and a circumferential edge, the circumferential edge having a first segment that is associated with the one fixed portion of the flap so as to remain at rest during an exhalation and having a second segment that is associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second segment of the circumferential edge also being located below the first segment when the filtering face mask is worn on a person, the flexible flap being mounted to the valve seat such that the one free portion of the flap is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice.

IN THE DRAWINGS:

Please replace the drawing sheet that contains Figs. 4-7 with the attached drawing sheet.

REMARKS

Claims 1-32 have been canceled, and claims 33-68 have been added to this application. Thus, claims 33-68 are now pending in this case.

The specification has been amended to make a number of corrections and changes to the text and to provide an identifying number for the seal surface 31 in the drawings.

Dated this 18th day of April, 2001.

Respectfully submitted,

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48317USA1N.033\PTO\Preliminary Amendment

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Changes to Specification

Page 3:

wherein, the fluid-permeable face mask can demonstrate a negative pressure drop when air is passed into the filtering face mask with a velocity of at least [0.8] 8 m/s under a normal exhalation test.

Page 7:

When a wearer of a filtering face mask **10** exhales, exhaled air passes through the mask body **12** and exhalation valve **14**. Comfort is best obtained when a high percentage of the exhaled air passes through exhalation valve **14**, as opposed to the filter media of mask body **12**. Exhaled air is expelled through valve **14** by having the exhaled air lift flexible flap **24** from valve seat **26**. Flexible flap **24** is attached to valve seat **26** at a first stationary portion **28** of flap **24**, and the remaining circumferential edge of flexible flap **24** is free to be lifted from valve seat **26** during exhalation. The circumferential edge segment that is associated with the stationary portion **28** remains at rest during an exhalation. As the term is used herein, "flexible" means the flap can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., FIG. 5). A flap that is not self-supporting will tend to drape towards the ground at about 90 degrees from the horizontal.

As shown in FIGs. 3 and 4, valve seat **26** has a seal ridge **30** that has a seal surface 31 to which the flexible flap **24** makes contact when a fluid is not passing through the valve **14**. An orifice **32** is located radially inward to seal ridge **30** and is circumscribed thereby. Orifice **32** can have cross-members **34** that stabilize seal ridge **30** and ultimately valve **14**. The cross-members **34** also can prevent flexible flap **24** from inverting into orifice **32** under reverse air flow, for example, during inhalation. When viewed from a side elevation, the surface of the cross-members **34** is slightly recessed beneath (but may be aligned with) seal [ridge **30**] surface 31 to ensure that the cross members do not lift the flexible flap **24** off seal [ridge **30**] surface 31 (see FIG. 3).

Page 10:

Valve seat **26** preferably is made from a relatively light-weight plastic that is molded into an integral one-piece body. The valve seat can be made by injection molding techniques. The surface 31 of the seal ridge **30** that makes contact with the flexible flap **24** (the contact or seal surface) is preferably fashioned to be substantially uniformly smooth to ensure that a good seal occurs. The contact surface preferably has a width great enough to form a seal with the flexible flap **24** but is not so wide as to allow adhesive forces caused by condensed moisture to significantly make the flexible flap **24** more difficult to open. The width of the contact surface, preferably, is at least 0.2 mm, and preferably is in the range of about 0.25 mm to 0.5 mm.

Page 14:

Exhalation valve **14** can be provided with a valve cover to protect the flexible flap **24**, and to help prevent the passage of contaminants through the exhalation valve. In FIG. [6] 7, a valve cover **50** is shown which can be secured to exhalation valve **14** by a friction fit to wall **44**. Valve cover **50** also can be secured to the exhalation valve **14** by ultrasonic welding, an adhesive, or other suitable means. Valve cover **50** has an opening **52** for the passage of a fluid. Opening **52** preferably is at least the size of orifice **32**, and preferably is larger than orifice **32**. The opening **52** is placed, preferably, on the valve cover **50** directly in the path of fluid flow **36** so that eddy currents are minimized. In this regard, opening **52** is approximately parallel to the path traced by the free end **38** of flexible flap **24** during its opening and closing. As with the flexible flap **24**, the valve cover opening **52** preferably directs fluid flow downwards so as to prevent the fogging of a wearer's eyewear. All of the exhaled air can be directed downwards by providing the valve cover with fluid-impermeable side walls **54**. Opening **52** can have cross-members **56** to provide structural support and aesthetics to valve cover **50**. A set of ribs **58** can be provided on valve cover **50** for further structural support and aesthetics. Valve cover **50** can have its interior fashioned such that there are female members (not shown) that mate with pins **41** of valve seat **14**. Valve cover **50** also can have a surface (not shown) that holds flexible flap **24** against flap-retaining surface **40**. Valve cover **50** preferably has fluid impermeable ceiling **60** that increases in height in the direction of the flexible flap from the fixed end to the free end. The interior of the ceiling **60** can be provided with a ribbed or coarse pattern or a release surface to prevent the free end of the flexible flap from adhering to the ceiling **60** when moisture is present on the ceiling or the flexible flap. The valve cover design **50** is fully shown in U.S. Design Patent Application 29/000,382. Another valve cover that also may be suitable for use on a face mask of this invention is shown in Design Patent Application 29/000,384. The disclosures of these applications are incorporated here by reference.

Page 20:

The exhalation valve of Example 1 was mounted to a 3M 8810 filtering face mask such that the exhalation valve was positioned on the mask body directly opposite to where a wearer's mouth would be when the mask is worn. The airflow through the nozzle was increased to approximately 80 l/min to provide an airflow velocity of [0.9] 8.3 meters per second (m/s). At this velocity, zero pressure drop was achieved inside the face mask. An ordinary person will exhale at moderate to heavy work rates at an approximate air velocity of about [0.5 to 1.3] 5 to 13 m/s depending on the opening area of the mouth. Negative and relatively low pressures can be provided in a face mask of this invention over a large portion of this range of air velocity.

Examples	*Volume Flow (liters/minute)*	*Pressure Drop (Pa) Nozzle Area: [1.81 cm] 18.1 cm^2*	*Pressure Drop (Pa) Nozzle Area: 2.26 cm^2*	*Pressure Drop (Pa) Nozzle Area: 0.96 cm^2*	*% Total Flow Nozzle Area: 18.1 cm^2*	*% Total Flow Nozzle Area: 2.26 cm^2*	*% Total Flow Nozzle Area: 0.95 cm^2*
8	12	9.02	8.92	8.92	1	2	2
9	24	15.09	14.21	11.17	19	24	39
10	48	18.62	14.99	4.31	30	60	87
11	60	20.48	15.09	-1.76	56	68	102
12	72	22.34	14.80	-7.55	61	73	112
13	80	24.01	14.41	-12.94	62	77	119

Changes to the Abstract

[An exhalation valve **14** for a filtering face mask **10** has a flexible flap **24** that makes contact with a curved seal ridge **30** of a valve seat **26** when the valve **14** is in the closed position. The curvature of the seal ridge **30** corresponds to a deformation curve exhibited by the flexible flap **24** when secured as a cantilever at one end and exposed at its free portion to a uniform force and/or a force of at least the weight of the free portion of the flexible flap. A seal ridge curvature corresponding to a flexible flap exposed to uniform force allows the flexible flap **24** to exert a generally uniform pressure on the seal ridge to provide a good seal. A seal ridge curvature corresponding to a flexible flap exposed to a force of at least the weight of the flap's free portion allows the flexible flap **24** to be held in an abutting relationship to the seal ridge **30** under any static orientation by a minimum amount of force, thereby providing a face mask **10** with an extraordinary low pressure drop during an exhalation.]